RECEIVED AT DRUG SAFETY SURVEILLANCE
19-FEB-1998-0740

McNEIL CONSUME
FORT WASHI

Page

Individual Safety Report
3031846-2-00

5/93

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
Case 244 In confidence	52 yrs or Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- (X) death unknown (mo/day/yr)
- ( ) life-threatening
- (X) hospitalization - initial or prolonged
- ( ) disability
- ( ) congenital anomaly
- ( ) required intervention to prevent permanent impairment/damage
- ( ) other:

3. Date of event: unknown (mo/day/yr)

4. Date of this report: 02/06/98 (mo/day/yr)

5. Describe event or problem

Case # 244 received from the [redacted] 1996 case fatality data.
See attached case report form provided by [redacted]

FEB 19 1998

6. Relevant tests/laboratory data, including dates

See attached case report form provided by [redacted]

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

See attached case report form provided by [redacted]

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#1 hydrocodone/acetaminophen 10/650 mg
#2

2. Dose, frequency & route used
#1 unknown dose, po
#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1 unknown dates or duration
#2

4. Diagnosis for use (indication)
#1 intentional misuse
#2

5. Event abated after use stopped or dose reduced
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)
#1 Unknown
#2

7. Exp. date (if known)
#1 Unknown
#2

8. Event reappeared after reintroduction
#1 ( ) Yes ( ) No (X) N/A
#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)
See attached case report form provided by [redacted]

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
McNeil Consumer Products Company
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-233-7820

3. Report source (check all that apply)
- ( ) foreign
- ( ) study
- (x) literature
- ( ) consumer
- (x) health professional
- ( ) user facility
- ( ) company representative
- ( ) distributor
- ( ) other:

4. Date received by manufacturer (mo/day/yr): 01/30/98

5.
(A) NDA # 17-552
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)
- ( ) 5-day (X) 15-day
- ( ) 10-day ( ) periodic
- (X) Initial ( ) follow-up #

8. Adverse event term(s)
OVERDOSE
COMA
HYPOTENSION
ACIDOSIS LACTIC
LIVER FAILURE
APNEA
SHOCK
DEATH

9. Mfr. report number: 0929724A

E. Initial reporter

1. Name, address & phone #
[redacted] MD
[redacted] Centers
Suite [redacted] Avenue
[redacted]

2. Health professional? (X) Yes ( ) No

3. Occupation: physician

4. Initial reporter also sent report to FDA: ( ) Yes ( ) No (X) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

RECEIVED AT DRUG SAFETY SURVEILLANCE
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Individual Safety Report
3031846-2-00

[redacted] FATALITY: 1996 [redacted]

Case Number:	**244**
Age:	52 yrs
Substances:	Acetaminophen/hydrocodone
Chronicity:	Chronic
Route:	Ingestion
Reason:	Int misuse
Pre-Hospital Arrest?	No

A 52 yo disabled (chronic back pain) white female was brought unresponsive into the ED of a rural hospital. She had been found unconscious by her family next to bottles of hydrocodone/acetaminophen 10/650 mg (#50) and carisoprodol 350 mg #(100).

An acetaminophen level was 30 mcg/ml, drawn at a time unknown in relation to ingestion. The patient was profoundly acidotic, with a ph of 6.85. Naloxone was administered to a total dose of 8.8 mg IV without effect.

On transfer to a referral hospital, the patient was comatose and had the following vital signs: BP 75/43 mm Hg, P 125 BPM, R 27/min and T (rectal) was 97.8°. An initial blood gas showed: pH 6.95, pCO2 14, and bicarbonate 3 mmol/L. Blood lactic acid level was 25.9 mg/dL. Urine toxicology screen was positive for opiates and barbiturates. Additional lab work included a sodium of 159 mmol/L, potassium of 3.6 mmol/L, chloride of 115 mmol/L and bicarbonate of (5 mmol/L. Prothrombin time was 35.7 seconds and ammonia was 225 umol/L (nl = 11-35).

The patient was treated with endotracheal intubation, plus aggressive treatment of fluid/electrolyte and acid-base abnormalities. She was given a loading dose of mucomyst. She experienced rapid progression of multi-system organ failure which culminated in her demise within 24 hours of admission.

Cause of death was attested to be by her attending physician: acute polydrug overdose with lactic acidosis, hepatic failure, respiratory failure and cardiogenic shock. Although the poisoning was a polydrug overdose, the most important event leading to death was considered to be delayed presentation of acetaminophen-induced liver failure.